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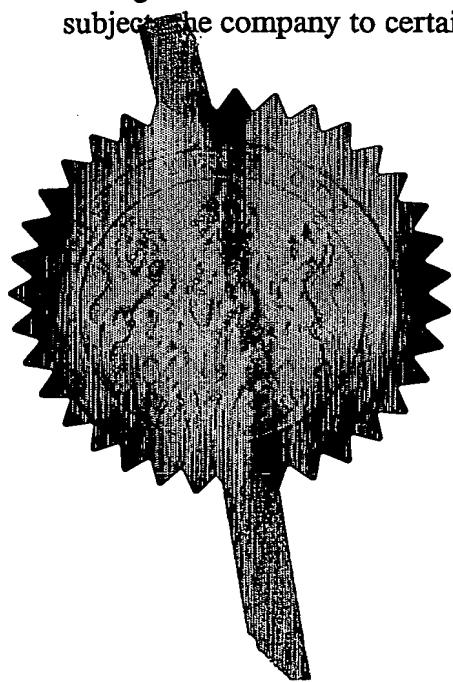
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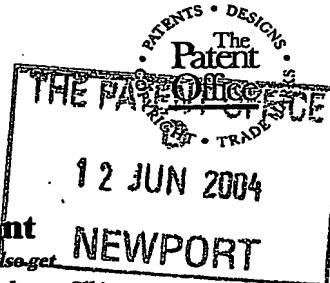


Signed

Dated 16 December 2004

Stephen Hordley

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14 JUN 04 E903225-2 D10007
P01/7700 0.00-0413139.7 NDNE**Request for grant of a patent**

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1. Your reference

P3184a GB PRO

2. Patent application number

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0413139.7

12 JUN 2004

3. Full name, address and postcode of the or of
each applicant (underline all surnames)
 Passion For Life Healthcare Limited
 55 High Street
 Epsom
 Surrey KT19 8DH

8889453001

Patents ADP number (if you know it)

If the applicant is a corporate body, give the
country/state of its incorporation

United Kingdom

4. Title of the invention

Composition and Delivery System

5. Name of your agent (if you have one)

NOVAGRAAF PATENTS LIMITED

 "Address for service" in the United Kingdom
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 THE CRESCENT
 54 BLOSSOM STREET
 YORK YO24 1AP

Patents ADP number (if you know it)

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6. Priority: Complete this section if you are
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this application is a divisional application or
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- a) any applicant named in part 3 is not an inventor, or
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Continuation sheets of this form

Description 17

Claim(s)

Abstract

Drawing(s)

1 21

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10. If you are also filing any of the following, state how many against each item.

Priority documents

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Statement of inventorship and right to grant of a patent (Patents Form 7/77)

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11. I/We request the grant of a patent on the basis of this application.

Signature(s)

NOVAGRAAF PATENTS LIMITED

Date 11 June 2004

12. Name, daytime telephone number and e-mail address, if any, of person to contact in the United Kingdom

Peter Wilson (Dr)

01904 610586

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COMPOSITION AND DELIVERY SYSTEM

The invention relates to a composition for delivery of ingredients active *in situ* to a site on the mucous membranes of the nose or throat of a human or animal subject. The invention also relates to a method of preparation of such a composition, and to such a composition within a suitable delivery system. The invention in particular relates to an aerosolisable composition for use as a nasal or throat spray, to a method of preparation of such an aerosolisable composition, and to such a composition as an aerosolisable spray within a suitable delivery system.

Various delivery systems are known by which an active ingredient, such as a medicament or the like, can be delivered to an active site on the mucous membranes of the nose or throat. These include active ingredients in solution or liquid suspension, for oral administration by swallowing, gargle or rinse; active ingredients within a soluble solid carrier such as a pastille, lozenge or the like; and active ingredients in solution or suspension in an aerosolisable form, for use in a nasal or throat spray. The present invention is particularly effective in the provision of preparation suitable for an aerosolisable delivery, and examples of nasal and throat sprays are given. However, it should be understood that the invention is not limited to aerosolisable delivery systems, and that any other delivery systems, for example, based on active ingredients in solution or suspension in a liquid, or in a solid soluble carrier form, could be envisaged.

The general principle of using a spray directed at the mucous membranes of the nose or throat to deliver an active ingredient thereto is well established. A spray can provide an effective way to deliver a controlled and effective dose

of an active ingredient to a desired site in the nose or throat of a subject in particular to produce a desired physical or pharmacological effect. Such active ingredients might include for example decongestants, breath-fresheners and deodorisers, lubricants, antibacterial and antiseptic compositions, anti-
5 histamines, anti-inflammatory compositions, analgesics, medicaments to treat to specific conditions associated with the mucous membrane *in situ*, and medicaments intended to be absorbed across the mucous membrane for active effect elsewhere.

10 In particular, throat sprays are known as a means to deliver a composition intended to reduce the impact of snoring in a subject. Such compositions are intended primarily to tackle the social effect of the snore. That is, they are intended particularly to attenuate the noise of the snore, and to reduce its impact, in particular as perceived by other parties, rather than to treat any
15 underlying condition as such. Compositions are prepared comprising one or more lubricant active ingredients intended to keep the soft tissues and mucous membranes of the nose and pharynx moist and lubricated and thus reduce the noise associated with snoring, and in particular the noise associated with snoring which arises from the soft tissues of the throat.

20 Various known preparations exist for this purpose. These typically include a mixture of various active nature oils designed to be sprayed into the throat onto the mucous membranes at the back of the throat and thereby to provide for a lubrication and/ or moisturising effect on the soft tissues of the throat.
25 Alternative compositions also exist primarily directed at alleviating the noise attributable to nasal snoring and applied as a nasal spray onto the nasal membranes though these can be less effective, particularly in cases where the nasal snoring is attributable at least in part to nasal congestion. Compositions may include additional function other than that of keeping the mucous

membrane moist, for example including active ingredients having decongestant properties.

Such compositions can be limited in effectiveness, particularly over time. It is inherent in the nature of the problem that they are intended to solve that sustained activity over a sustained period, and most preferably overnight is desirable. However in practice the effect of spraying lubricants on to the mucous membranes of the nose or throat is likely to be more short lived as the active ingredient is rapidly lost from the desired site through for example evaporation, the action of secreted nasal mucus and saliva etc.

To limit this problem a means to stabilise the active ingredient *in situ* on the mucous membrane is required, and this has led in some current spray compositions to the use of liposome technology to bind the active ingredients more effectively. Even so, there is still a tendency for the activity of such ingredients to decrease significantly with time, so that the sprays offer an effectiveness which in practice is very much less than the duration of a full night's sleep.

It is an object of the present invention to provide a composition in particular but not limited to an aerosolisable composition for nasal or buccal application which mitigates some or all of the above disadvantages of prior art systems.

It is a particular object of the present invention to provide a composition in particular but not limited to an aerosolisable composition relying on known and/or new active ingredients which serves to stabilise the active ingredients *in situ* on the mucous membranes of the nose or throat for a sustained period of time.

It is a particular object of the present invention to provide a composition in particular but not limited to an aerosolisable composition relying on known and/or new active ingredients which ensures that activity of the active ingredient is sustained for an increased period of time, and in particular retains 5 reasonable activity levels overnight.

It is a particular further object of the invention to provide a delivery system for such a composition, in particular but not limited to a nasal or throat spray delivery system for an aerosolisable composition.

10

Thus according to the invention in its broadest aspect there is provided a composition for nasal or buccal application comprising a distribution of multilayer microparticles in an inactive base, and at least one ingredient having activity on the mucosa of the nose/ throat adsorbed within the layers of 15 the microparticles so as to be progressively released over time in use.

In accordance with the invention, multilayer microparticles are distributed within an inactive base which serves as the means for delivery of the microparticles to the mucosa of the nose/throat. The chosen base is not 20 directly pertinent to the invention, and various alternatives will suggest themselves. The invention is particularly suited to use as an aerosolisable composition for nasal or buccal application by means of a spray. In this case the composition comprises a suspension of microporous microparticles in a suitable liquid base. A spray is ideally suited to applying a controlled dose to 25 the required site, for example on the membranes at the back of the throat, where the active ingredient is then retained for slow release.

In the alternative, the composition comprises a suspension in a suitable liquid base for direct oral or nasal administration, for example by oral ingestion,

gargle, rinse or the like. In a further alternative the composition comprises a distribution of multilayer microparticles in a soluble solid or gel base, in particular for oral administration, for example as a pastille, lozenge or the like, the base material being such as to dissolve within the mouth and liberate the 5 microparticles to allow them to find their site on the mucous membranes of the throat.

The multilayer microparticles are selected to exhibit good adhesion to the mucous membranes of the nose and/or throat, and are small enough to be 10 aerosolisable as a spray. The layers are structured to give slow release of the active ingredient over the desired time period, so that the spray gives sustained activity over time, for example providing for measurable activity (eg at least 50% of initial base line activity level) for a sustained period of four or more hours, and ideally of for example 6 to 12 hours, to give overnight 15 effectiveness. The microparticles are sized and shaped in accordance with the required delivery means, for example to form an effectively aerosolisable fluid phase in suspension as a composition in accordance with the invention. The microparticles in particular comprise generally spherical particles or microspheres. Particle sizes in the range 0.1 to 50 μm , and for example 1 to 20 μm are likely to be preferred. In the preferred embodiment particle levels of 10-25% within the composition are likely to be suitable to optimise effect whilst obtaining an aerosolisable fluid phase in suspension.

The microparticles are adapted to facilitate slow release of the active 25 ingredients over time, and are found inherently to show good adhesion to the mucous membranes of the nose and/or throat. The net result of this is that the active ingredients are stabilised *in situ* on the mucous membranes, and that the active ingredients are then released steadily at the site where they are required. Loss of activity over time is significantly reduced compared with conventional

sprays relying for example on liposome technology, and it becomes possible to maintain reasonable levels of activity over the sort of time scale necessary to be effective overnight, and for example to assist in providing a relatively less disturbed night's sleep.

5

Whilst the invention is not limited by any particular theory of operation, it is considered that the adhesive effect arises in particular in that the microparticles generally comprise polar structures with a positive surface charge. Adhesion to the mucosa of the nose or throat is particularly effective
10 as the tissue in the nose or throat tends to be negatively charged.

The particles are multilamellar and can present a mixture of hydrophilic and lipophilic surfaces depending on the chosen active ingredients. These surfaces serve to bind the active ingredients within the layers and facilitate slow release
15 as each layer is successively out by enzymes in the nose or mouth to release the active ingredient within the layer. In particular the microparticles comprise multiple layered structures formulated with one or more of and preferably examples of all of: surfactant layers (comprising any type of surfactant such an anionic, non-anionic, cationic, phospholipids and the like);
20 polar media such as water, glycerol, PEG; and active binding materials comprising hydrophilic materials in the polar layers and hydrophobic materials in the surfactant layers. In the preferred embodiment where the microparticles are microspheres such a multiple layered structure in particular comprises substantially concentric spheroidal surfaces. These multiple layered
25 structures are particularly suited to the controlled release of active ingredients adsorbed within the microparticles over a controlled period of time.

The microparticles thus preferably comprise multi-lamellar structures of surfactant layers, which are able to encapsulate active ingredients to a very

high degree for protection and controlled slow release. The surfaces of the microparticles are such as to be adapted to enhance adhesion to human skin, and hence to fix the particles in position on the mucous membranes of the nose and/ or throat as the active ingredients are progressively released. In a 5 particularly effective mechanism, slowly, over time, the layers of the microsphere are dispersed successively by the mucosal enzymes and fluids, releasing the active ingredients as they do so. Slow release of active ingredients *in situ* is thereby effected.

10 Suitable compositions include 30 to 50% surfactant, 30 to 50% polar medium, and 10 to 60% active binding agent, comprising hydrophilic and hydrophobic agents as appropriate.

15 Microparticles such as are above described have been extensively developed for cosmetic application. They are found to give good skin adhesion to stabilise colour, gloss etc in the desired position, increase effect life of the cosmetic product *in situ* etc. They have not hitherto been described in relation to the controlled binding for slow release of physically active ingredients at the active site on the mucous membrane of the nose or throat of the human, 20 non-human mammal or other animal subject in the manner of the present invention. However, in accordance with the present invention, they are found to be surprisingly effective for such an application, both because the microparticles bind effectively to the membranes to ensure good delivery *in situ*, and because they lend themselves ideally to the controlled slow release of 25 the microencapsulated active ingredients.

Adsorbed within of the microparticles on or between the surfaces of the multiple layers thereof are one or more different active ingredients having activity on the mucous membranes of the nose and/or throat as the case may

be. In a preferred embodiment, for application to limit the physical effects of snoring, these active ingredients include at least one active ingredient to lubricate and/or moisturise the mucous membrane, to ease breathing and reduce snoring. However the invention is not limited to active ingredients with this activity, but could include active ingredients with other activities, for example physical (moisturising, lubricating, cooling etc) or pharmacological (for example decongestant, anti-histamine, anti-bacterial, anti-inflammatory, analgesic etc).

10 In the preferred embodiment the active ingredient comprises one or more lubricant/moisturisers to lubricate and/or moisturise the nasal and/or throat membranes as the case may be. In particular, the composition is for nasal application for example as a nasal spray composition and the active ingredient comprises one or more lubricant/moisturiser to lubricate and/or moisturise the nasal membranes. Alternatively, the composition is for buccal application for example as a throat spray composition and the active ingredient comprises one or more lubricant/moisturiser to lubricate and/or moisturise the throat membranes.

15 20 Natural oils and the like are especially preferred ingredients. For example, the active ingredient may comprise a mixture of lubricating and/or moisturising oils selected from the group comprising: Hyaluronic acid, Glycerol, Calendula officinalis flower extract, Guar hydroxypropyltrimonium chloride, Xanthan gum, Cellulose gum, Sodium chloride, Olivum (olive oil), Helianthus annus (sunflower oil), Prunus dulcis (sweet almond oil), Sesamum indicum (sesame oil), Aloe vera, Aloe barbadensis, Euphorbium officinarum, Oxymetazoline hydrochloride, Lactoperoxidase and combinations thereof.

Additionally or alternatively the composition preferably comprises as an active ingredient at least one decongestant, being an ingredient having a chemical or pharmacological or other effect of reducing airway congestion and/or limiting further airway mucus production. In particular, the additional 5 ingredient comprises a nasal decongestant selected to clear and/ or limit the further production of nasal mucus. The active ingredient may be a natural oil, a pharmacalogically active synthetic preparation, or combination. Suitable examples include: Hyaluronic acid, Calendula officinalis flower extract, Thymus vulgaris, Menthyl lactate, Mentha piperita (or any other mint/ 10 peppermint derivative or extract), Lavendula augustifolia (or any other lavender derivative or extract), Phenylephrine hydrochloride, Pseudephedrine, Ascorbic acid (vitamin C), Acerola, Rumex crispus (yellow dock), Eucalyptus globulus (eucalyptus oil), Levmetamfetamine, Oxymetazoline hydrochloride, Propylhexedrine, Xylometazoline hydrochloride, Zincum Gluconicum, 15 menthol, eugenol, cineol, rosemary oil (rosmarinus), summer savory oil (satureia hortensis), wild thyme oil (thymus serpyllum), firtree oil, lavendula vera oil, geranium oil, cinnamon oil, Hawthorn extract (crataegus oxyacantha), rose hips extract (rosa canina), cypress oil (cupressus sempervirens) and combinations thereof.

20

In an embodiment, the composition is adapted for nasal application, and incorporates the nasal decongestant as above described together with at least one lubricant and/or moisturiser. This is particularly effective. Systems which rely on lubrication and/or moisturising alone will be entirely ineffective 25 against nasal snoring where a subject has an infectious, irritated or allergic breathing congestion, and such infectious, irritated or allergic breathing congestion is likely to exaggerate the undesirable effects of nasal snoring. For the same reason, a composition adapted for nasal application may also include an active ingredient with anti-histaminic action.

The microparticles fix the active ingredients adsorbed inside each shaped layer in position on the membranes of the nose or throat of the user, protect the active ingredients and slowly release them *in situ*, and might also assist in 5 providing a desired lubricating effect.

10 The composition comprises a dispersion of multilamellar microparticles as above described having active ingredients encapsulated on the surface layers thereof and dispersed within a liquid base so as to aerosolisable for application. The Liquid base may be aqueous, for example comprising a saline or otherwise generally isotonic solution.

15 Further active or inactive ingredients might be provided either encapsulated within the microparticles or separately in suspension or solution within the liquid base for various purposes. For example additional active ingredients might include further ingredients having any further desired physical or pharmacological activity on the mucous membranes of the nose and/ or throat, including without limitation decongestants, breath-fresheners and deodorisers, lubricants, antibacterial and antiseptic compositions, anti-histamines, anti- 20 inflammatory compositions, analgesics, and other medicaments and non-medicaments. Inactive ingredients might further be added in suspension or solution for example to stabilise or preserve the liquid base, balance the pH of the liquid base, bring the liquid base to closer approximation to isotonic concentration etc.

25

The composition in accordance with the invention is preferably provided for use as a spray, and in particular as a nasal or throat spray. Thus, in accordance with the invention in a further aspect there is provided a spray dispenser, and in particular a nasal spray dispenser, comprising a base reservoir container

containing a composition as hereinbefore described and a spray delivery system for example comprising a pump spray, the reservoir being fluidly connected to the spray delivery system, and the spray delivery system being adapted to draw, aerosolise and deliver a controlled dose from the reservoir to
5 a subject in use.

In particular the spray delivery system might comprise a dose fluid reservoir to measure and dispense a predetermined dose of spray from the base reservoir in the container. Suitable spray technology will be familiar and is not
10 specifically pertinent to the invention.

Alternatively, the composition in accordance with the invention is provided as a liquid suspension of microparticles for direct oral administration, for example by ingestion, gargle or rinse. Further alternatively, the composition is
15 provided for oral administration distributed within a soluble solid or gel base, for example as a lozenge or pastille.

In accordance with the further aspect of the invention, a method of preparing a composition for the controlled delivery of an active ingredient over time *in situ* at the mucous membranes of the nose or throat of a human, non-human mammal or other animal comprises the steps of:
20 microencapsulating at least one ingredient having activity on the mucosa of the nose/ throat within or on the layer surfaces of a multilayer microparticle; distributing the ingredient within a suitable inactive base serving as a means to
25 deliver the microspheres to the active site.

In particular the method comprises preparing a spray composition by preparing a suspension of a plurality of such particles in a liquid base and filling a spray dispenser of suitable design with the suspension as above

described. Other features of the preparation method will be understood by analogy with the foregoing.

In accordance with the further aspect of the invention, a method of delivering 5 an active ingredient to the nose or throat of a human, non-human mammal or other animal subject for controlled release over time *in situ* at the mucous membranes of the subject comprises the steps of:

microencapsulating at least one ingredient having activity on the mucosa of the nose/ throat within or on the layer surfaces of a multilayer microparticle; 10 distributing the microparticles in an inactive base material, for example suspending in a liquid base or distributing in a soluble solid base; administering the composition to the subject in such manner that the microparticles are directed towards a desired site on the mucus membrane of the subject.

15

In a particular preferred embodiment the method comprises the specific steps of:

preparing a suspension of a plurality of such particles in a liquid base; forming an aerosol spray from the said suspension; 20 directing the aerosol spray at a desired site on the mucous membrane of the subject.

The active ingredient may have a therapeutic effect, for example exhibiting pharmacological or other physiological activity, or may have a non-therapeutic 25 effect, for example in the reduction of the social effects of snoring and the like. Thus in one alternative, the method applies an active ingredient which is directly physiologically or pharmacologically active to treat a specified medical condition and therefore comprises a method of medical treatment. In another alternative the method comprises the application of an active

ingredient which has a physical non-medical activity not specifically being a method of medical or therapeutic treatment. In a particular example of the latter, an active ingredient comprises a lubricant and/or moisturiser to lubricate or moisturise the mucous membranes of the nose or throat of a user to

5 minimise the effects of snoring. The method thus serves not to treat any underlying condition which might be contributing to the snoring as such, but rather to attenuate the noise produced thereby and so provide relief to third parties from the anti-social effects of the noise associated therewith.

10 By way of example only, figure 1 illustrates a suitable pump spray dispenser suitable for use with a composition in accordance with the invention intended for use as a throat spray.

In figure 1, the composition, comprising an aqueous suspension of

15 multilamellar microparticles incorporating active ingredients as above described, is stored in a hygienic plastic or other bottle 2. The bottle has a screw threaded neck 4 onto which a pump dispenser unit 6 may be attached via a threaded portion 5. The thread may provide for the unit to be unscrewed for refilling or may lock. Other connections could be substituted.

20 The pump dispenser unit 6 comprises a chamber portion 8 and a depressible button 7 at the top. The chamber portion 8 includes a dose reservoir in fluid communication with a primary fluid reservoir in the bottle 2, for example by means of an internal tube or conduit (not shown), and optionally including

25 valve and like flow control arrangements in familiar manner. The dose reservoir in the chamber portion is sized to hold a single dose of fluid, and the act of depressing the button 7 and allowing it to return to an undepressed position serves to prime the device by drawing such a single dose into the dose reservoir from the stock in the bottle 2 in generally familiar manner.

The unit in Figure 1 is designed to apply fluid composition in accordance with the invention to the throat. Accordingly, the delivery system includes a deployable delivery tube 11 shown deployed horizontally for use, and which is 5 rotatable out of a stowed configuration 11a by means of the pivoting unit 12. The delivery tube 11 comprises a hollow conduit to deliver a dose of fluid from the dose reservoir in the chamber portion via a nozzle 13 to the throat of a user. Depression of the button 7 acts in the usual way to expel the measured dose from the dose reservoir via the tube to the user. The nozzle 13 may be 10 configured in familiar manner to create a suitable aerosolised spray of the fluid to ensure even distribution and desired spread at the application site on the user's throat.

15 A controlled dose is applied directly to the active site. The patient is encouraged not to swallow for, for example, 40 seconds to allow the microspheres to adhere to the mucous membranes, and thus a stabilised slow release is enabled directly at the desired active site.

20 The unit in Figure 1 is a throat sprayer as an example only. It will readily be understood that the invention similarly applies to a nasal spray. Suitable modifications to the sprayer for nasal use will readily suggest themselves. In particular the nozzle is likely to point vertically, and may be incorporated as an upward extension of the button.

25 Further by way of example, three example compositions are described, the first suitable for use as a nasal spray and the second and third as a throat spray.

Example A – Nasal Spray

	PURIFIED WATER	79,10 %
5	SODIUM CHLORIDE	0,85 %
	SODIUM CARBOXYMETHYLCELLULOSE	0,02 %
	XANTHAN GUM	0,03 %
	SPHERULITE PARTICLES	20,00 %
10	SPHERULITES contain :	
	Water	
	Sorbitan stearate	
	Polysorbate 60	
	Hydroxypropyltrimonium chloride	
15	Calendula glycerin extract	3.375 %
	Thymus vulgaris	0.050 %
	Lavandula angustifolia	0.050 %
	Menthyl lactate	0.175 %

Example B – Throat Spray

	PURIFIED WATER	74,54 %
5	GLYCERIN	15,00 %
	XANTHAN GUM	0,10 %
	POTASSIUM SORBATE	0,25 %
	CITRIC ACID	0,11 %
	SPHERULITE PARTICLES	10,00 %
10		
	SPHERULITES contain:	
	Water	
	Sorbitan stearate	
	Polysorbate 60	
15	Hydroxypropyltrimonium chloride	
	Olive oil	3.000 %
	Mint oil	2.000 %
	Sunflower oil	1.500 %
	Vitamin E	1.000 %
20	Glycerin	10.000 %
	Potassium sorbate	0.150 %
	Sodium Hyaluronique powder nasal grade	0.100 %

Example C – Throat Spray

	PURIFIED WATER	58.54 %
5	GLYCERIN	10.00 %
	XANTHAN GUM	0.1 %
	POTASSIUM SORBATE	0.25 %
	CITRIC ACID	0.11 %
	MICROCRYSTALLINE CELLULOSE	1.00 %
10	SPHERULITE PARTICLES	30.00 %

SPHERULITES contain:

	Water	62.18 %
	Sucroesters and Guar Hydroxypropyltrimonium	25.00 %
15	Olive oil	2.00 %
	Mint oil	3.00 %
	Grapeseed oil	1.50 %
	Tocopherol Acetate	1.00 %
	Glycerin	5.00 %
20	Potassium sorbate	0.15 %
	Citric Acid	0.07 %
	Sodium Hyaluronate	0.10 %

These compositions are examples only illustrative of but not limiting on the
25 overall scope of the invention.

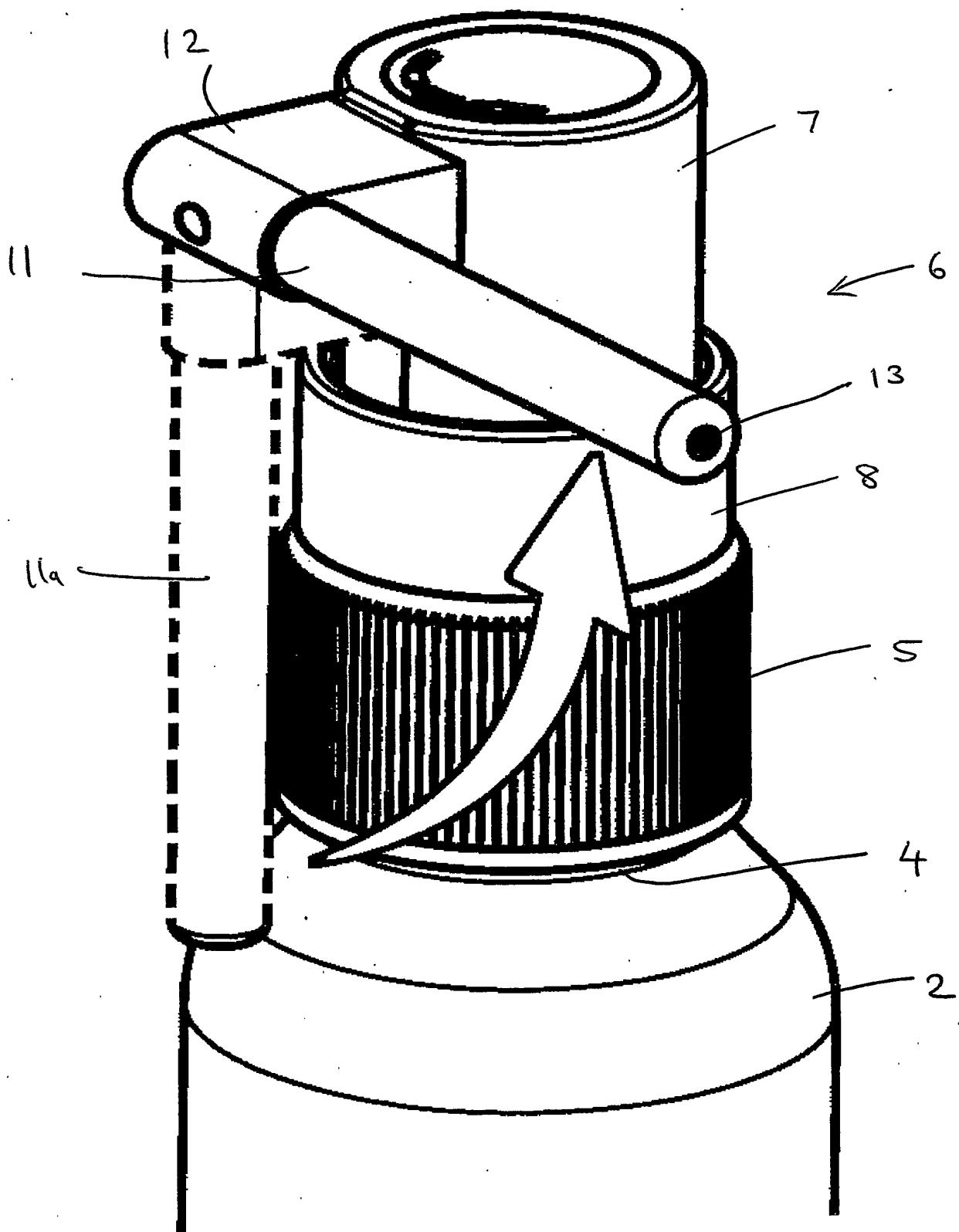


Figure 1

Document made available under the Patent Cooperation Treaty (PCT)

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